

REMARKS

Claims 24-38 are pending in the present application. Claims 24, 25, 33 and 38 have been amended. No new matter has been added by these amendments.

Reconsideration and allowance of the present application in view of the remarks below are respectfully requested.

I. INFORMATION DISCLOSURE STATEMENT AND CO-PENDING APPLICATIONS THAT SET FORTH SIMILAR SUBJECT MATTER

In compliance with the Examiner's request to provide documents cited by Applicants on the PTO-1449 form filed on February 4, 2002, Applicants submit herewith a copy of the submitted PTO-1449 form and copies of references AV-BK, attached hereto as Exhibit C. It is respectfully requested that References AV-BK be considered and entered into the file of the above-identified application.

Also, the Examiner requested a list of all co-pending applications that sets forth similar subject matter as the present claims. Applicants submit that the co-pending applications to the present application are U.S. application serial no. 10/022,607, filed December 17, 2001 and U.S. application serial no. 10/603,115, filed June 24, 2003. A copy of the pending claims for each co-pending application is enclosed as Exhibit D and Exhibit E, respectively.

II. FORMAL OBJECTIONS

The Examiner has objected to the specification on the ground that the continuing data is not updated with the current status of the parent cases and are not included in a single paragraph. The specification has been replaced with a paragraph that sets forth updated continuing data, as suggested by the Examiner. It is respectfully requested that the Examiner's objection to the specification be withdrawn.

The Examiner has objected to the drawings of Figures 8-11 for failing to show any significant or discernable structure. Submitted herewith are formal drawings of Figures 8-11 in response to the Examiner's objection. It is respectfully requested that the Examiner's objection to the drawings be withdrawn, and the formal drawings be accepted and entered into the file of the application.

The Examiner has objected to the abstract as not being drawn to the presently

claimed invention. The abstract has been rewritten to briefly describe the presently claimed invention. It is respectfully requested that the Examiner's objection to the abstract be withdrawn.

The Examiner has objected to the word "prosthesis" in claims 24 and 33. The word "prosthesis" in claims 24, 33 and 35 has been replaced by -- prosthesis --. It is respectfully submitted that the Examiner's objection to the informalities of claims 24 and 33 have been overcome.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 112

The Examiner has rejected claims 24-37 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner has objected to the term "stent" in claims 24 and 33 for lack of antecedent basis¹. The term "stent" has been replaced with the term "prosthesis". Support for this amendment is found, *inter alia*, at page 2, lines 5-9 and page 2, lines 25-28. Withdrawal of this rejection, and reconsideration and allowance of claims 24-37 are respectfully requested.

In claim 38, the phrase "and wherein the average particle size of the heparin is" has been replaced with --having an average particle size -- to clarify and more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Withdrawal of this rejection, and reconsideration and allowance of claim 38 are respectfully requested.

IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 102

The Examiner has rejected Claims 24-33 and 35-37 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,716,981 to Hunter *et al.* ("Hunter *et al.*"). Applicants respectfully submit that Hunter *et al.* does not anticipate the present invention because it does not teach each and every element of the claimed invention. As detailed below, the cited reference neither describes nor suggests the presently claimed subject matter.

Claims 24-33 and 35-37 are directed to an implantable medical prosthesis having at least one opening in which at least a portion of the prosthesis is covered by a coating. The coating comprises a polymeric material, which incorporates a biologically

¹ The Examiner has also objected to the phrase "the average particle size" in claim 35 for lack of antecedent basis. It is respectfully submitted that claim 35 does not have the phrase "the average particle size." It is the understanding of Applicants that the Examiner's objection refers to claim 38 of the phrase "the average particle size" for lack of antecedent basis.

active material with an average particle size of about 4-6 μm . The coating also adheringly conforms to the prosthesis so as to preserve the opening when the prosthesis is expanded.

Hunter *et al.* discloses an anti-angiogenic composition which comprises an anti-angiogenic factor and a polymeric carrier. (Col. 12, lines 23-25). Contrary to the Examiner's statement on page 3 of the Office Action, Hunter *et al.* does not disclose that the biologically active material or anti-angiogenic drug should be about 4-6 μm . As such, Hunter *et al.* does not teach or suggest the present invention.

The Examiner has rejected claims 24, 25, 27-36, and 38 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,591,227 issued to Dinh *et al.* ("Dinh *et al.*"). Dinh *et al.* discloses a drug eluting fibrin stent which has a polymer coating-layer and a fibrin top-layer (Col. 2, lines 36 - 56). The Examiner contends that Dinh *et al.* anticipates the claim language where the particle size claimed can be 0 microns such that the solutions with molecular size components read on the claim language. Applicants submit that Dinh *et al.* does not teach or suggest particulate therapeutic substances, let alone the claimed range of the average particle size.

Also, the Examiner contends that the coating which preserves openings as claimed is inherently met by Dinh's coating that is so thin that will not significantly increase "the profile of the stent". Applicants submit that "the profile of the stent" as recited in Dinh *et al.* refers to the overall diameter of the stent but does not teach or suggest that the openings of the stent are preserved. Dinh *et al.* does not teach or suggest that the coating adherently conform to the surface of the stent so as to preserve the openings of the stent or prosthesis. The Examiner is directed to Dinh *et al.*'s description regarding the profile of the stent at col. 3, lines 6-9; col. 7, lines 7-9.

"The overall coating should be thin enough so that it will not significantly increase the profile of the stent for intravascular delivering by catheter."

Dinh *et al.* refers to "the profile of the stent" as the overall diameter of the coated stent so that it is still suitable of being placed in the blood vessels using a catheter. Accordingly, "the profile of the stent" in Dinh *et al.* refers to the overall diameter of the stent, which if changed, will not be suitable to be placed in the blood vessels using a catheter. Similar to Hunter *et al.*, Dinh *et al.* is silent as to whether the coating occludes openings of the sidewalls of the stent or whether the coating adherently conforms to the prosthesis and

that the coating thus formed preserves the opening of the prosthesis when it is expanded.

Furthermore, to establish that a claim element is inherently present in a reference, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Continental Can Company USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). Here, no evidence has been presented to show that the missing teaching of a preserved openings of the present invention is necessarily present in Dinh *et al.* Therefore, Dinh *et al.* does not inherently teach or suggest that the coating adheringly conform to the prosthesis and that the coating thus formed preserves the opening of the prosthesis when it is expanded. Hence, the claimed invention is not anticipated by Dinh *et al.*

Hence, since it does not disclose each and every element of the present invention, Dinh *et al.* does not anticipate the present invention.

V. CONCLUSION

Applicants submit that claims 24-38 satisfy all of the criteria for patentability and are in condition for allowance. Accordingly, Applicants respectfully request entry of the foregoing amendments and remarks into the file of the above-identified application.

Respectfully submitted,

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Enclosures